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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WALGREEN CO., THE KROGER CO., SAFEWAY INC., HEB GROCERY COMPANY LP and SUPERVALU INC.,	
Plaintiffs,	**Civil Action No.**
v.	**JURY TRIAL DEMANDED**
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA LP, ASTRAZENECA AB, and AKTIEBOLAGET HASSLE,	
Defendants.	

COMPLAINT

Plaintiffs Walgreen Co., The Kroger Co., Safeway Inc., HEB Grocery Company LP and Supervalu Inc. (collectively, "Plaintiffs") bring this civil action against Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca LP, AstraZeneca AB, and Aktiebolaget Hassle (collectively "AstraZeneca" or "Defendants"), and allege as follows:

Nature of The Case

1. This is a civil antitrust action seeking treble damages and other relief arising out of AstraZeneca's unlawful, anticompetitive scheme to block the entry of generic competition and thereby to illegally maintain its monopoly power in the United States market for extended-release metoprolol succinate, which market is comprised of the pharmaceutical AstraZeneca sells under the brand name Toprol-XL, together with its AB-rated generic equivalents. Toprol-XL is an extended-release drug approved by the U.S. Food & Drug Administration ("FDA") for treating hypertension, angina, and congestive heart failure (together, herein referred to as "heart disease"). AstraZeneca sells this drug in 25 mg, 50 mg, 100 mg, and 200 mg dosages.

AstraZeneca's scheme allowed it to charge supracompetitive prices, prevented prices of extended-release metoprolol succinate from falling to the competitive level that would have been reached subsequent to the entry of generic competition, and thereby caused Plaintiffs to pay overcharges on their purchases of extended-release metoprolol succinate.

2. Defendants engaged in a scheme involving misconduct before the United States Patent and Trademark Office ("PTO") in order to obtain two patents – U.S. Patent No. 5,001,161 (the "'161 Patent") and U.S. Patent No. 5,081,154 (the "'154 Patent") (collectively, the "Patents") – which, in the absence of such conduct, would not have issued. Defendants proceeded improperly to procure the listing of the Patents with the FDA, in order to position themselves to assert patent infringement claims against, and to block the market entry of, any potential competitor seeking FDA approval to manufacture and sell a competing, generic version of Toprol-XL.

3. Defendants then instituted a series of objectively baseless lawsuits against potential competitors, for the sole purpose of forestalling generic competition. In 2003 and 2004, Defendants filed multiple lawsuits against companies seeking approval from the FDA to market generic forms of Toprol-XL, asserting infringement of the Patents, even though Defendants knew that the Patents had been improperly procured and were invalid, and that no reasonable claim of infringement could be asserted based upon them.

4. Defendants instituted these lawsuits not for any legitimate purpose, but because they knew the mere filing of such litigation would raise barriers to the entry of generic competition, including by automatically delaying the FDA's granting of final marketing approval to the generic manufacturers. Without FDA approval, generic manufacturers cannot bring their products to market.

5. By their unlawful acts, Defendants willfully maintained their monopoly power over Toprol-XL and generic, bioequivalent forms of the drug, *i.e.* the extended-release metoprolol succinate "molecule," and thereby benefited from hundreds of millions of dollars in ill-gotten revenues.

6. Absent Defendants' unlawful conduct, less expensive generic versions of Toprol-XL would have been on the market earlier than they were. Through their unlawful conduct, Defendants deprived Plaintiffs of access to substantially lower-priced extended-release metoprolol succinate. Defendants have caused Plaintiffs to overpay for extended-release metoprolol succinate by millions of dollars.

7. The antitrust claims asserted by Plaintiffs in this case are the subject of an existing class action pending in this Court, *In re Metoprolol Succinate Direct Purchaser Antitrust Litigation*, Civil Action No. 06-52-GMS, and the statute of limitations applicable to them has been tolled since June 2006 as a result of the pendency of that class action.

Parties

8. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its principal place of business in Deerfield, Illinois. Walgreen owns and operates retail stores in several states at which it dispenses prescription drugs to the public, including Toprol-XL. Walgreen brings this action in its own behalf and as the assignee of Cardinal Health, Inc. ("Cardinal"), a pharmaceutical wholesaler, which during the relevant period purchased Toprol-XL directly from AstraZeneca for resale to Walgreen and which has assigned its claims arising out of those purchases to Walgreen.

9. Plaintiff The Kroger Co. ("Kroger") is an Ohio corporation having its principal place of business in Cincinnati, Ohio. Kroger owns and operates retail stores in several states at which it dispenses prescription drugs to the public, including Toprol-XL. Kroger brings this

action in its own behalf and as the assignee of Cardinal, which during the relevant period purchased Toprol-XL directly from AstraZeneca for resale to Kroger and which has assigned its claims arising out of those purchases to Kroger.

10. Plaintiff Safeway Inc. ("Safeway") is a Delaware corporation having its principal place of business in Pleasanton, California. Safeway owns and operates retail stores in several states at which it dispenses prescription drugs to the public, including Toprol-XL. Safeway brings this action in its own behalf and as the assignee of McKesson Corporation ("McKesson"), a pharmaceutical wholesaler, which during the relevant period purchased Toprol-XL directly from AstraZeneca for resale to Safeway and which has assigned its claims arising out of those purchases to Safeway.

11. Plaintiff HEB Grocery Company, LP ("HEB") is a Texas limited partnership having its principal place of business in San Antonio, Texas. HEB owns and operates retail stores in several states at which it dispenses prescription drugs to the public, including Toprol-XL. HEB brings this action in its own behalf and as the assignee of Cardinal, which during the relevant period purchased Toprol-XL directly from AstraZeneca for resale to HEB and which has assigned its claims arising out of those purchases to HEB.

12. Supervalu Inc. ("Supervalu") is a Delaware corporation having its principal place of business in Eden Prairie, Minnesota. Supervalu owns and operates retail stores in several states at which it dispenses prescription drugs to the public, including Toprol-XL. Supervalu brings this action in its own behalf and as the assignee of McKesson, which during the relevant period purchased Toprol-XL directly from AstraZeneca for resale to Supervalu and which has assigned its claim arising out of a portion of those purchases to Supervalu.

13. Defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of Delaware, which distributes, markets, sells, and/or profits from pharmaceutical products including Toprol-XL throughout the United States. Its United States corporate headquarters is located at 1800 Concord Pike, Wilmington, DE. AstraZeneca Pharmaceuticals LP is a subsidiary of AstraZeneca PLC, and was created as a result of the merger of Zeneca Pharmaceuticals and Astra Pharmaceuticals LP in the U.S.

14. Defendant AstraZeneca LP is a limited partnership organized and existing under the laws of Delaware, with its principal place of business at Wilmington, Delaware. AstraZeneca LP holds an approved New Drug Application from the United States Food and Drug Administration ("FDA") for metoprolol succinate preparations with extended-release, which it sells under the brand name Toprol-XL. AstraZeneca LP is a U.S. subsidiary of AstraZeneca PLC.

15. Defendant AstraZeneca AB, formerly known as Astra Aktiebolaget, is a corporation organized and existing under the laws of Sweden, having its principal place of business at S 151 85 Sodertalje, Sweden.

16. Defendant Aktiebolaget Hassle is a corporation organized and existing under the laws of Sweden, having its principal place of business at Molndal, Sweden. Aktiebolaget Hassle is a wholly-owned subsidiary of AstraZeneca AB.

Jurisdiction And Venue

17. This Court has jurisdiction over the subject matter of this civil action pursuant to 28 U.S.C. §§ 1331 and 1337.

18. Venue is proper in this judicial district under 28 U.S.C. § 1391 and 15 U.S.C. § 22, because Defendants transact business, committed an illegal or tortious act, have an agent,

and/or are found within this District, and/or because a substantial portion of the events described below have been carried out in this District.

Interstate Trade And Commerce

19. At all material times, one or more Defendants manufactured and sold substantial amounts of Toprol-XL in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

20. At all material times, Toprol-XL manufactured and sold by one or more Defendants was shipped across state lines and sold to customers located outside its state of manufacture.

21. At all material times, Defendants transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Toprol-XL.

22. In furtherance of their efforts to maintain monopoly power over Toprol-XL and its generic equivalents willfully, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

23. Defendants' efforts willfully to maintain monopoly power over Toprol-XL and its generic equivalents willfully, as alleged herein, have substantially affected interstate and foreign commerce.

BACKGROUND

A. Branded Drugs

24. Under the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, approval by the Food and Drug Administration ("FDA") is required before a new drug may be sold in interstate commerce. Premarket approval for a new drug must be sought by filing a new

drug application with the FDA, under either section 355(b) or section 355(j) of the Act, demonstrating that the drug is safe and effective for its intended use.

25. In 1984, Congress amended the Food, Drug and Cosmetic Act by enacting the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Amendments or the Hatch-Waxman Act. The Hatch-Waxman Act simplified the regulatory hurdles for prospective generic drug manufacturers by eliminating the need for generic companies to file lengthy and costly New Drug Applications ("NDAs") in order to obtain FDA approval. Instead, such companies are permitted to file Abbreviated New Drug Applications ("ANDAs") and to rely on the safety and effectiveness data already supplied to the FDA by the brand-name manufacturer. The Hatch-Waxman Act also added a number of patent-related provisions to the statutory scheme, as described below. Congress's principal purpose in enacting the Hatch-Waxman Act was "to bring generic drugs onto the market as rapidly as possible." *Mova Pharmaceuticals Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998).

26. New drugs that are approved for sale by the FDA are sometimes protected by a patent or patents, which provide the patent owner with the exclusive right to sell that drug in the United States for the duration of the patent or patents involved, plus any extensions. Under 21 U.S.C. § 355(b)(1), a patent holder seeking FDA approval for a new drug is required to file with the FDA "the patent number and expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Patent information received by the FDA with respect to approved drugs is published in a book entitled "Approved

Drug Products With Therapeutic Equivalence Evaluations," commonly known as the "Orange Book," where it can be found and consulted by future FDA applicants.

27. Federal regulations impose strict limitations on the types of patents that an NDA holder can submit to the FDA for listing in the Orange Book. *See generally* 21 C.F.R. § 314.53. One such limitation is imposed by 21 C.F.R. § 314.53(b), which explicitly prohibits NDA holders from listing any patent in the Orange Book unless a claim of infringement could reasonably be asserted on the basis of such a patent.

28. Despite the FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has regrettably become common for brand-name pharmaceutical companies to list in the Orange Book any and every patent they can obtain, so as to force generic manufacturers to file what, as described below, is commonly known as a Paragraph IV certification.

29. The FDA does not police the listing of patents. The FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing in the Orange Book. The FDA has stated that it lacks the resources and expertise to review the patents submitted in connection with NDAs. *See* 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information").

30. As a result, as numerous courts have recognized, the FDA's role in the patent listing process is purely ministerial, and it relies entirely upon the good faith of the NDA holder submitting the patent for listing.

B. Generic Drugs

31. Generic drugs are drugs that the FDA has found to be bioequivalent to their corresponding brand name drugs. A generic drug provides identical therapeutic benefits and has the same side effects and safety profile as its corresponding brand name drug.

32. Generic drugs invariably cost substantially less than the branded drugs to which they are bioequivalent. Typically, the first generic version of a brand name drug is sold at a substantial discount to the brand, followed by increasingly steeper discounts as more generics of that particular molecule enter the market.

33. Under the Hatch-Waxman Act, a generic drug manufacturer may seek expedited FDA approval to market a generic version of a brand name drug with an approved NDA by filing an Abbreviated New Drug Application ("ANDA"), pursuant to 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand name drug.

34. To obtain FDA approval of an ANDA (and thus the legal right to sell a generic version of brand-name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA does not infringe any patent listed in the Orange Book as claiming the brand-name drug.

35. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications pursuant to 21 U.S.C. §355(j)(2)(A)(vii). Four types of certifications are available:

I. The brand name manufacturer has not filed patent information with the FDA (a "Paragraph I Certification");

II. The patent or patents listed in the Orange Book have expired (a "Paragraph II Certification");

III. The patent will expire on a date in the future, and the generic manufacturer does not seek to market its generic version of the drug prior to the date of expiration (a "Paragraph III Certification"); or

IV. The patent is invalid or not infringed by the generic manufacturer's product (a "Paragraph IV Certification").

36. If a drug manufacturer's ANDA contains certifications under Paragraphs I, II or III, the ANDA may be filed five years after the NDA for the referenced drug was approved. If the ANDA contains a paragraph IV certification, the ANDA can be filed 4 years after the NDA for the referenced drug was approved. *See* Frequently Asked Questions for New Product Exclusivity at www.fda.gov/cder/about/smallbiz/exclusivity.htm.

37. If a generic manufacturer files a Paragraph IV Certification asserting that the patent is invalid or will not be infringed, the brand-name manufacturer has the opportunity to delay the generic manufacturer's receipt of final approval, and, thus, its ability to come to market. This is because a generic manufacturer filing a Paragraph IV Certification must promptly give notice of this fact to both the NDA owner and the owner of the patent(s) at issue.

38. Submitting a Paragraph IV Certification with respect to a valid patent that would be infringed by the ANDA filer's proposed generic drug constitutes a "technical act of infringement" under Hatch Waxman, which creates a right of action to assert such infringement and gives the patent holder forty-five days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. § 271(e)(2). *See* 21 U.S.C. § 355(j)(5)(B)(iii). If such a suit is initiated, the FDA's approval of the ANDA is automatically stayed for up to thirty months. 21 U.S.C. § 355(j)(5)(B)(iii).

39. Because of this thirty-month stay, the mere filing of an infringement action in response to a Paragraph IV Certification, regardless of the action's underlying merit, gives the brand-name company the functional equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor, without the brand company's ever having to establish likelihood of success on the merits, irreparable harm, that the balance of hardships tips in its favor, or that the public good is served by the blocking of entry. Indeed, as a practical matter the brand name company wins the lawsuit simply by filing it, as it automatically protects its monopoly for up to two-and-a-half years, and possibly longer, while the infringement action winds its way through the court system. (And the brand name company has an incentive to stall the progress of this action.) There are no disgorgement provisions for profits earned during the thirty-month period of exclusivity if a court eventually determines that the suit was without merit.

40. An improper Orange Book listing also has additional anticompetitive effects, because the first generic company to file an ANDA with a Paragraph IV Certification is, upon FDA approval, granted a 180-day period of marketing exclusivity in relation to other generic manufacturers. 21 U.S.C. § 355(j)(5)(B)(iv). This 180-day exclusivity period is awarded to the first Paragraph IV Certification ANDA filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the Paragraph IV certification. Absent an improper Orange Book listing, no Paragraph IV Certification would be required and, thus, no generic company would receive any 180-day exclusivity; rather, multiple generic competitors would enter the market simultaneously.

41. Defendants were at all times fully familiar with their ability to delay the entry of generic competition by the improper manipulation of the patent listing and pre-approval litigation provisions of the Hatch-Waxman Act.

Defendants' Anticompetitive Conduct

42. AstraZeneca has successfully forestalled generic competition to Toprol-XL from entering the market – thereby delaying purchasers the benefits of cheaper, generic extended-release metoprolol succinate products – by obtaining the Patents, which it did not deserve, through intentional and fraudulent misrepresentations and omissions, by fraudulently listing the Patents in the Orange Book, and by bringing and maintaining sham Patent Lawsuits based thereon.

A. Defendants' Improper Procurement of Patents

43. Defendants have asserted that the '161 Patent and the '154 Patent cover Toprol-XL and bar generic competition.

44. The '161 Patent issued on March 19, 1991, with a single claim: "A pharmaceutical composition comprising metoprolol succinate together with a sustained release pharmaceutically acceptable carrier."

45. The '154 Patent issued on January 14, 1992, with a single claim: "Metoprolol succinate."

46. The named inventors on both the '161 and '154 Patents are Curt H. Appelgren and Eva C. Eskilson. However, Appelgren and Eskilson were not the inventors of metoprolol succinate, which had been first made at AstraZeneca before either of them joined the company and more than ten years before patent applications claiming the compound were filed in the PTO naming them as inventors.

47. As explained in detail below, when Appelgren and Eskilson tried to claim formulations of metoprolol succinate for their new employer after leaving the employ of AstraZeneca, AstraZeneca contested their right to do so and asserted its ownership to rights to metoprolol succinate in a complaint filed in the Swedish Patent Office that alleged that metoprolol succinate had been invented by its employee, Toivo Nitenberg, and disclosed in confidence to Appelgren and Eskilson. Several months later, Appelgren and Eskilson agreed to drop metoprolol succinate from their application, assign rights to AstraZeneca, file a new application directed to metoprolol succinate and assign the new application to AstraZeneca.

48. In the early 1980s, Appelgren and Eskilson were employed at AstraZeneca's AB Hassle division in Molndal, Sweden. Among their duties, Appelgren and Eskilson participated in a project to develop new controlled-release formulations of metoprolol. Their duties, however, had nothing to do with the identification, synthesis, or invention of different salts of metoprolol.

49. Under the organization and procedures within the AstraZeneca organization at the time, responsibility for synthesis of alternative compounds rested with a group employed by Astra Pharmaceutical Production AB, located in Sodertalje, Sweden. Neither Appelgren nor Eskilson conceived of or synthesized metoprolol succinate. Rather, that compound was supplied to the group of which Appelgren and Eskilson were members by chemists employed by AstraZeneca in Sodertalje, including Lars Lilljequist.

50. In his deposition taken in the Patent Lawsuits against potential generic competitors, Appelgren admitted that metoprolol succinate was not a newly developed product at AstraZeneca, but was an "old," known compound supplied to the product development group.

51. The other inventor, Eskilson, could not recall at her deposition why she was named an inventor of metoprolol succinate. Eskilson testified that she had never made metoprolol succinate, nor could she recall ever telling anyone else to make metoprolol succinate.

52. At the end of 1982, Appelgren resigned from Hassle to form his own company, Lejus Medical AB ("Lejus"). Appelgren was a founder and 25% owner of Lejus.

53. Several months later, Eskilson joined Appelgren at Lejus, and Appelgren and Eskilson began to work on developing a sustained release formulation of quinidine sulphate for a U.S. company unrelated to AstraZeneca.

54. On January 10, 1984, Lejus filed a Swedish patent application (SE8400085, the "Swedish Application") naming Appelgren and Eskilson as the inventors based on the sustained release formulation they had developed for quinidine sulphate at Lejus. When listing potentially useful pharmaceutical agents for their sustained release formulation, Appelgren and Eskilson included metoprolol succinate. Although Appelgren and Eskilson knew of metoprolol succinate from their work at Hassle, they did not believe they were violating any duty of confidentiality by disclosing it in the Swedish Application because they did not believe it was a new compound or that they were its inventors.

55. The Lejus application was published in July of 1985 and came to the attention of Hassle and its parent, AstraZeneca AB, which on October 21, 1985, filed a complaint with the Swedish Patent Office asserting that Appelgren and Eskilson were not the inventors of metoprolol succinate and that the compound was invented by Toivo Nitenberg, a Hassle employee. At this point, Lejus had already filed a corresponding U.S. patent application (U.S. Serial No. 690,197 (the "'197 Application")), which ultimately issued as U.S. Patent No. 4,780,318 (the "'318 Patent").

56. To settle Hassle's complaint, Lejus, Appelgren, and Eskilson agreed to assign Hassle any rights to metoprolol succinate in an agreement dated April 21, 1986 (the "Lejus/Hassle Agreement"). The Lejus/Hassle agreement was negotiated on behalf of Hassle and AstraZeneca at least by employees of AstraZeneca 's patent department, including Bengt Wurm.

57. In March of 1988, Lejus filed the U.S. patent application (U.S. Serial No. 172,897 (the "'897 Application")) that eventually issued as the '161 Patent, tracking almost exactly the agreed-upon language from the Lejus/Hassle agreement. Thereafter, Lejus assigned this application to Hassle.

58. By the time this application was filed in March of 1988, more than one year had passed since publication of Lejus's Swedish Application naming metoprolol succinate and claiming sustained-release pharmaceutical formulations containing metoprolol succinate. Thus, Hassle knew that unless the applications issuing as the '161 and '154 Patents could rely on the filing date of the Swedish Application, any new claims in the '161 and '154 Patents to metoprolol succinate or sustained-release formulations of it would be unpatentable, inter alia, as anticipated by the Swedish Application, pursuant to 35 U.S.C. §§ 102(b) and 119(a). They would have been unpatentable as anticipated because of other prior art as well, including an article published in 1987 and two other patent applications filed by Hassle.

59. Thus, Hassle knew that if it identified Nitenberg as the inventor of the '161 and '154 Patents, then because Nitenberg is not an inventor on the '897 application and the Swedish Application, Hassle would not be able to rely on the filing date of the Swedish Application for the '161 and '154 Patents and those patents would be rejected by the PTO or invalidated in litigation.

60. Hassle knew that in order to obtain U.S. patents directed to metoprolol succinate and avoid the bar of the published Swedish Application, it had to file deceptively in the names of Appelgren and Eskilson in order to make a claim of priority. Hassle did just this.

61. Appelgren, Eskilson, the representatives prosecuting the applications, employees of Hassle and Astra, and others involved in the prosecution of the '161 and '154 Patents knew that Appelgren and Eskilson were not the joint inventors of metoprolol succinate or the subject matter claimed in the Patents.

62. During the prosecution of the '161 and '154 Patents, Defendants did not disclose to the PTO its complaint to the Swedish Patent Office dated October 21, 1985, the Lejus/Hassle Agreement, the facts leading to these documents, or that Toivo Nitenberg had made metoprolol succinate in 1971.

63. During the prosecution of the '161 and '154 Patents, Defendants intentionally made other material misrepresentations and omissions, including in submitting a declaration of an employee, John Anders Sandberg (the "Sandberg Declaration"). Among other things, although the Sandberg Declaration extols the virtue of metoprolol succinate for use in once-daily, controlled-release preparations, Defendants did not explain that its alleged virtues were unique to a particular formulation developed by Sandberg, unrelated to any work done by Appelgren and Eskilson. The Sandberg Declaration also omits material information known to Dr. Sandberg and Defendants about prior art and the performance of other metoprolol salts.

64. These omissions and/or misrepresentations were purposeful. They were made with an intent to deceive and did, in fact, deceive the PTO, resulting in the issuance of the '161 and '154 Patents.

B. Defendants' Sham Orange Book Listings

65. Despite Defendants' knowledge that the '161 and '154 Patents were invalid and/or unenforceable, Defendants caused the patents to be listed in the Orange Book as covering Toprol-XL and as reasonably giving rise to a claim of infringement. Defendants did not withdraw these Orange Book listings even after being provided with clear proof that they were improper.

66. Defendants knew that the listing of patents in the Orange Book as applying to Toprol-XL would raise entry barriers, including increased costs, for drug manufacturers seeking to market generic versions of Toprol-XL.

67. Defendants knew that, under the Hatch-Waxman Act, if they sued to enforce patents listed in the Orange Book, they would (a) receive the equivalent of an automatic injunction that would last up to thirty months, or more, (b) bar generic competitors from marketing extended-release metoprolol succinate products without having to show a likelihood of success on the merits, and regardless of the invalidity or unenforceability of the listed patents or the baselessness of the suit, and (c) delay FDA action, attention to, and approval of ANDAs filed by generic competitors.

68. Defendants' decisions to cause the patents to be listed, not to inform the FDA that the '161 and '154 Patents were invalid, and not to withdraw the Orange Book listings, were intentionally deceptive.

C. Defendants' Sham Patent Lawsuits

69. Despite Defendants' knowledge that the '161 and '154 Patents were invalid and/or unenforceable, Defendants commenced a series of lawsuits asserting infringement of these patents against the following companies seeking to market bioequivalent, generic versions of

Toprol-XL: KV Pharmaceutical Co., Andrx Pharmaceuticals, LLC, Andrx Corp., and Eon Labs, Inc. (collectively, the "Generic Manufacturers"). These lawsuits were ultimately transferred to the United States District Court for the Eastern District of Missouri for pretrial proceedings ("the Patent Lawsuits").

70. Knowing that the Patent Lawsuits were objectively baseless, because, among other things, they were based on invalid and/or unenforceable patents, Defendants nonetheless commenced and maintained them deceptively, in bad faith, and with the specific intent and subjective motivation to prevent the Generic Manufacturers from selling competing extended-release metoprolol succinate products.

71. Defendants knew that even though ultimately they could not expect success on the merits of the Patent Lawsuits, filing the lawsuits would nonetheless enable them automatically to bar the generic manufacturers from coming to market for up to thirty months or more, under 21 U.S.C. § 355(j)(5)(b)(iii), and would otherwise dissuade and forestall potential generic competition from entering the market.

72. Defendants' lawsuits were shown to be a sham. On January 17, 2006, United States District Judge Rodney W. Sippel granted summary judgment for the Generic Manufacturers, determining, *inter alia,* that any reasonable jury was bound to find that (1) the '161 and '154 Patents were invalid for double-patenting and anticipation based on Claim 8 of the '318 Patent, and (2) the '161 and '154 Patents were unenforceable because of AstraZeneca 's misconduct in not informing the patent examiner about the dispute regarding inventorship while prosecuting the patents. On the latter point, Judge Sippel found that the inventorship issue was "highly material" to patentability and that AstraZeneca 's intent to deceive was "clearly present."

73. Defendants' conduct during the Patent Lawsuits further evinces their anticompetitive intent. For example, Judge Sippel noted that, during the litigation, Defendants "maintained a pattern of submitting witness declarations that contradict their own prior deposition testimony."

74. Judge Sippel's holding that the '154 patent was invalid for double patenting was affirmed by the Federal Circuit. *See In re Metroprolol Succinate Patent Litigation*, 494 F.3d 1011 (Fed. Cir. 2007). AstraZeneca did not appeal Judge Sippel's ruling that the '161 patent was invalid for double patenting. *Id.* at 1015. The Federal Circuit held that there were issues of fact concerning AstraZeneca's intent to deceive the PTO, and reversed and remanded the inequitable conduct ruling for further proceedings. *Id.* In the meantime, prior to the Federal Circuit decision, generics entered the market. Upon remand, the patent litigants settled.

Effects on Competition

75. Defendants' exclusionary conduct delayed generic competition to Toprol-XL and enabled Defendants to sell Toprol-XL without generic competition. But for Defendants' conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Toprol-XL much sooner than they were marketed.

76. The generic manufacturers that sought to sell generic Toprol-XL have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products. Eon, which was acquired by Novartis in mid-2005, for example, had a history of achieving high approval rates for its ANDAs, usually within twelve to thirteen months of filing an ANDA.

77. Eon had publicly affirmed its intention and ability to begin selling generic Toprol-XL upon approval of its ANDA. However, Defendants' unlawful conduct caused the ANDA approval process to be delayed by the FDA, and caused the generic manufacturers to divert

resources from their ANDA applications and to expend unnecessary resources on litigation. Another potential generic manufacturer, Andrx, had its pending drug applications placed on hold, which likely would not have affected its generic Toprol-XL ANDA absent Defendants' causing delay.

78. Absent the Patent Lawsuits, the Generic Manufacturers and the FDA would have had reason to, and would have, focused and directed resources into the ANDA approval process for generic extended-release metoprolol succinate. Such focus and resources would have brought earlier FDA approval and marketing of generic Toprol-XL.

79. The FDA expeditiously approves ANDAs when the generic product that is the subject of the ANDA is not the subject of a patent infringement litigation under the Hatch-Waxman Act. For example, when an ANDA filer makes a Paragraph III Certification, certifying that it will only market the drug at issue upon expiration of a patent listed as applying to the drug in the Orange Book, FDA approval of the ANDA typically occurs on the very same day the patent expires.

80. In essentially every instance since the year 2000 involving a brand-name drug coming off patent for which an ANDA filer certified that it would market a generic version of the brand-name drug only upon expiration of the relevant patent (*i.e.*, a Paragraph III Certification), the FDA approved the generic applicant the very day (or in a few instances, within one or two days) of the expiration date of the patent. The ANDAs were consistently timely filed and approved regardless of the magnitude of the brand-name drug's annual sales. The relative size of the annual Toprol-XL sales in the U.S. – approximately $900 million in 2003 – would only have made this market an even more attractive target for generic companies in the absence of the costs and delays of patent litigation. Accordingly, absent Defendants' conduct here,

generic drug manufacturers would have expeditiously filed ANDAs, and the FDA would have promptly and timely approved these ANDAs, permitting entry at the first legally available time, and substantially before the date on which actual entry occurred.

81. Absent Defendants' improper procurement of the '154 and '161 Patents, and their wrongful listing in the Orange Book, companies considering whether to submit an ANDA for extended-release metoprolol succinate would not have had to weigh the potential for, and costs of, litigation over the '154 and '161 Patents or the possibility that Defendants would be able to obtain an automatic stay for up to thirty months.

82. As a result of Defendants' conduct, additional generic manufacturers other than those that actually filed ANDAs were discouraged from and/or delayed in developing generic versions of Toprol-XL. Absent Defendants' improper procurement of the '154 and '161 Patents, and their wrongful listing in the Orange Book, the cost-benefit and return-on-investment calculations facing potential generic entrants would have been far more favorable toward investigating and developing a generic Toprol-XL product. Absent the challenged conduct, therefore, there would have been several other drug companies readying generic Toprol-XL products for market, and the Generic Manufacturers may not have been the first ANDA filers.

83. Defendants' acts to delay the introduction into the U.S. marketplace of any generic version of Toprol-XL caused Plaintiffs to pay more than they would have paid for extended-release metoprolol succinate, absent Defendants' illegal conduct.

84. Typically, generic versions of brand-name drugs are initially priced significantly below their corresponding, AB-rated brand-name versions. As a result, upon generic entry, retail pharmacies rapidly substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably

plunge even further because of competition among the generic manufacturers, and the brand-name drug continues to lose even more market share to the generics. This price competition enables all retail pharmacies to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand-name drug at a reduced price. Consequently, brand-name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

85. If generic competitors had not been unlawfully prevented from entering the market earlier and competing with Defendants, Plaintiffs would have paid less for extended-release metoprolol succinate by (a) substituting purchases of less-expensive AB-rated generic extended-release metoprolol succinate for their purchases of more-expensive branded Toprol-XL, and/or (b) purchasing generic extended-release metoprolol succinate at lower prices sooner.

86. Thus, Defendants' unlawful conduct deprived Plaintiffs of the benefits of competition that the antitrust laws were designed to ensure.

ANTITRUST IMPACT UPON PLAINTIFFS

87. During the relevant period, Plaintiffs and/or Plaintiffs' assignors purchased substantial amounts of Toprol-XL from Defendants. As a result of Defendants' illegal conduct, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their extended-release metoprolol succinate requirements. Those prices were substantially greater than the prices that Plaintiffs would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Toprol-XL was artificially inflated by Defendants' illegal conduct and/or (2) Plaintiffs were deprived of the opportunity to purchase lower-priced generic versions of extended-release metoprolol succinate instead of higher-priced brand-name Toprol-XL.

88. As a consequence, Plaintiffs have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

MONOPOLY POWER

89. Defendants had monopoly power over Toprol-XL and its generic equivalents, i.e., the power to maintain the price of Toprol-XL at supracompetitive levels profitably without losing substantial sales. This monopoly power is evidenced by their ability to charge supracompetitive prices for Toprol-XL without losing sales during the period in which they lacked generic competition.

90. A significant, non-transitory price increase by Defendants of Toprol-XL would not have caused a significant loss of sales to other products.

91. Defendants sold Toprol-XL at prices well in excess of marginal costs and enjoyed supracompetitive profit margins.

92. Moreover, Defendants had, and exercised, the power to exclude competition.

93. To the extent that defining a relevant product market is necessary in this case, the relevant product market is Toprol-XL and its AB-rated generic equivalents.

94. The relevant geographic market is the United States.

95. At the times relevant to this Complaint, Defendants held a 100% share in the relevant product market in the United States.

CLAIM FOR RELIEF

Monopolization Under Section 2 of the Sherman Antitrust Act

96. Plaintiffs incorporate by reference the preceding allegations.

97. Defendants knowingly and intentionally engaged in an anticompetitive scheme designed to obtain the '161 and '154 Patents and to maintain their monopoly power. This

scheme included procuring the '161 and '154 Patents by deceptive conduct before the PTO, improperly listing the '161 and '154 Patents in the Orange Book, and improperly filing and prosecuting the baseless Patent Lawsuits against the Generic Manufacturers. Defendants' scheme was designed to delay the introduction of AB-rated, generic versions of Toprol-XL into the market.

98. By their scheme, Defendants intentionally and wrongfully maintained their monopoly power with respect to Toprol-XL in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiffs paid artificially inflated prices for their extended-release metoprolol succinate requirements.

99. Plaintiffs have been injured in their business or property by Defendants' antitrust violations. Their injury consists of having paid higher prices for their extended-release metoprolol succinate requirements than they would have paid in the absence of those violations. Such injury is of the type antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful. Plaintiffs are the proper entities to bring a case to recover overcharges resulting from Defendants' unlawful conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for judgment against Defendants and for the following relief:

A. A judgment for three times the damages actually sustained by Plaintiffs, as determined by a jury;

B. A declaration that Defendants have violated the antitrust laws in the ways described above;

C. The costs of this suit, including a reasonable attorneys' fee; and

D. Such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury of all claims so triable.

ASHBY & GEDDES

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